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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,103	04/12/2001	Aki Kitagawa	12372-002001	5320

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BOSTON, MA 02110

EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 01/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,103

Applicant(s)

KITAGAWA ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 26-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II (claims 12-25) in Paper No. 8 dated June 26, 2002 is acknowledged.
2. Claims 1-11 and 26-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8 dated June 26, 2002.

Objections/Rejections Set For the in Office Action dated July 25, 2002

3. Acknowledgment was made of applicant's claim for foreign priority based on applications filed in Japan on April 17, 2000 and July 5, 2000. However, applicant had not filed certified copies of the JP 2000-115091 and JP 2000-203850 applications as required by 35 U.S.C. 119(b).
4. The abstract of the disclosure was objected to because the title "Sustained Release Drug Composition" should be removed.
5. Claims 12-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. EP 0 913 149 A1 (Suzuki) in view of Igari et al US 5,344,644 (Igari).

Applicant's Response dated October 30, 2002

6. In the amendment filed November 1, 2002, the Abstract was amended. Claims 1-46 are pending. Claims 1-11 and 26-46 are drawn to a nonelected invention. An action on the merits of claims 12-25 is contained herein below.
7. Applicant's amendment dated October 30, 2002 has overcome the objection to the Abstract as set forth in the Office Action dated July 25, 2002.
8. In the amendment filed October 30, 2002, applicant presented arguments directed to the rejection of claims 12-25 under 35 U.S.C. 103(a).
9. The rejection under 35 U.S.C § 103(a), is maintained for the reasons of record set forth in the Office Action dated July 25, 2002.
10. Certified copies of the JP 2000-115091 and JP 2000-203850 applications as required by 35 U.S.C. 119(b) **have not** been received.

Response to Arguments

11. Applicant's arguments filed October 30, 2002 have been fully considered but they are not persuasive.

The examiner disagrees with applicant's assertion that the art of record "teaches away from the use of acid to precipitate the product". The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The reason or motivation to combine may often suggest doing what the inventor

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has done, but for a different purpose or to solve a different problem than that asserted by the inventor. It is not necessary in order to establish prima facie obviousness that the prior art suggest their combination to achieve the same advantage or result discovered by the applicant.

In response to applicant's argument that Suzuki and Igari fail to teach "lowering the pH", the examiner respectfully disagrees. Suzuki teaches all of the necessary steps required (e.g., providing a precipitating solution, lowering the pH, and collecting the insoluble product). Suzuki does not explicitly teach lowering the pH for the purpose of precipitating drug composition out of solution; however, one of ordinary skill in the art would recognize that the addition of an acidic solution would indeed lower the pH of the solution. The reference does not have to explicitly state what the reference specifically teaches. The reference is not silent with regard to pH manipulation. If acid is added pH is lowered. The limitation argued is indeed prima facie obvious. Furthermore, Igari teaches that the lowering the pH of sustained-release compositions below 4 will cause the formation of a precipitate (column 6, lines 43-52). [The compositions comprise a pharmaceutically active agent (column 3, lines 52-59). Pharmaceutically active agents which may be used include interferons (e.g. alpha, beta, gamma), interleukins (e.g. IL-2 to IL-11), erythropoietin, granulocyte colony stimulating factors, granulocyte-macrophage colony stimulating factors, thrombopoietin, insulin, growth hormones, and parathyroid hormone related peptide (columns 3-4). The composition may further comprise a mucopolysaccharide such as chondroitin sulfate, heparin, and keratan

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sulfate (column 5, lines 16-65). The composition may further comprise water-soluble proteins such as serum albumin, globulin, collagen, or gelatin (column 6, lines 7-15).]

The examiner disagrees with applicant's comments regarding Igari (column 6, lines 43-51). While the examiner agrees that the compositions described by Igari preferably have a pH between 4 and 8 in order to maintain a solution [no precipitate], one of ordinary skill in the art at the time of the invention would readily recognize that lowering the pH would indeed result in the formation of precipitates.

Applicant further argues, "compositions precipitate because they are insoluble in the aqueous preparatory solutions". The examiner agrees that the precipitates because of their insolubility in the preparatory solutions; however, Suzuki teaches adding acetic acid to the preparatory solutions. As noted by applicant, all of the compositions described by Suzuki are ultimately obtained by precipitation. It would have been obvious to one of ordinary skill in the art at the time of the invention to lower the pH (i.e. add acid) of the preparatory solution in order to precipitate the drug composition since Igari teaches that the lowering the pH of sustained-release compositions below 4 will cause the formation of a precipitate.

Conclusion

12. Claims 1-46 are pending. Claims 1-11 and 26-46 are drawn to a nonelected invention. Claims 12-25 are rejected. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

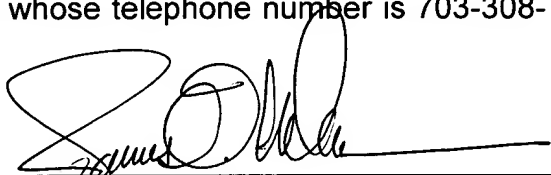
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623


James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
January 3, 2003